



**ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES**

**United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS**

NATIONAL PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

Johnson's 4 Fleas Protector 2% Spot-on Solution for Large Dogs

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Johnson's 4 Fleas Protector 2% Spot-on Solution for Large Dogs
Applicant	Alfamed
Active substance(s)	Pyriproxyfen
ATC Vetcode	QP53AX23
Target species	Dogs
Indication for use	Prevention of flea multiplication (adult and larval stages of <i>Ctenocephalides felis</i> sensitive to pyriproxyfen) in dogs weighing over 15 kg by inhibiting egg development for 3 months

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent application in accordance with Article 13c of Directive 2001/82/EC as amended.
-------------------------------------	---

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to Cyclo 60 mg Spot-On Solution for Large Dogs. The initial application for Cyclo 60 mg Spot-On Solution for Large Dogs was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

www.gov.uk/check-animal-medicine-licensed

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

www.gov.uk/check-animal-medicine-licensed